

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 50623.335	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on _____ Signature _____ Typed or printed Name _____	Application Number 10/663,568	Filed September 15, 2003	
	First Named Inventor Stephen Z. Wu		
	Art Unit 1615	Examiner Humera N. Sheikh	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the <input type="checkbox"/> applicant/inventor. <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) <input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>58,381</u> <input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number _____</p> <p> _____ Signature Jeffrey C. Talkington, Ph.D. _____ Typed or printed name (415) 954-0200 _____ Telephone number May 29, 2007 _____ Date</p>			
<input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Examiner: Humera N. Sheikh

Steven Z. Wu et al.

Serial No.: 10/663,568

Art Unit: 1615

Filed: September 15, 2003

Title: Microparticle Coated Medical Device

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Claims 25-33 are pending and have been twice rejected. Review of the rejections in this application is requested since the Examiner has ignored the legal requirements of a *prima facie* case of obviousness.

Claims 25-33 have been twice rejected for obviousness over WO 01/01890 A1 to Yang et al.

As indicated by the Examiner, Yang discloses a stent with “a coating disposed over at least a portion of the body, and an active agent releasably dispersed in at least part or portion of the coating.” The Examiner further stated that “the stent can be coated by spraying the stent with a solution or dispersion of polymer, active agent and solvent. The solvent can be evaporated, leaving a coating of polymer and active agent. The active agent can be dissolved and/or dispersed in the polymer. In some embodiments, the copolymer can be extruded over the stent body.”

Claim 25 reads “a coating layer disposed on the stent body, and polymeric particles containing a therapeutic substance embedded within the coating layer.” Claim 32 reads an “implantable substrate and a coating” such that “the coating includes particles of a polymeric material having a therapeutic substance added thereto.”

One criterion of a *prima facie* case of obviousness is that the combined references teach or a modified prior art reference teaches or suggests all claim limitations. MPEP 2143. Yang fails to teach or suggest all the limitations of claims 25 and 32.

Yang does not teach, expressly or inherently, polymeric particles containing a therapeutic substance embedded in a coating. There is no indication by Yang or the Examiner that the surface treatment techniques of Yang would result in the formation of polymer particles containing a therapeutic agent embedded in the coating. Yang does teach that a therapeutic substance can be dispersed in the polymer of a coating, however, there is no express or inherent teaching that the dispersed therapeutic substance is within polymeric particles. Additionally, although Yang teaches that the coating can include a blend of first and second co-polymers, there is no teaching or suggestion that the blend includes particles of one polymer dispersed within the other.

Another one of the requirements of a *prima facie* case of obviousness is that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. MPEP 2143. Indeed, “To support the conclusion that the claimed invention is directed to obvious subject matter...the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.” *Ex parte Clapp*, 227, U.S.P.Q 972, 973

The Examiner states that “given the explicit teachings of Yang et al., the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.” The Examiner states a conclusion without providing any support or argument for meeting the requirements stated above for a *prima facie* case of obviousness.

Since Yang does not teach or suggest all the claim limitations and the Examiner has not provided a suggestion nor motivation contained either in another reference(s) or in the knowledge generally available to one of ordinary skill in the art to modify Yang so that it teaches the above-mentioned claim limitations, the Examiner has failed to provide the requirements of a *prima facie* case of obviousness.

The Examiner considered these arguments in the Final Office Action dated April 4, 2007 finding them unpersuasive and suggesting that since Applicants had not defined the size of the particles, that the dispersion of agent within a polymer, as suggested by Yang, made the present invention obvious.

This is not the case. Applicants claim a drug loaded stent comprising particles containing therapeutic agent, and the lack of a size description does not negate this. Yang, in contrast, discloses a solution of polymer and solvent with therapeutic agent dispersed throughout.

Since the Examiner has failed to establish a *prima facie* case of obviousness, claims 25 and 32, and claims 26-31 and 33 dependent thereon, are allowable.

Claims 25, 26, 28, 29, 30 and 32 have been twice rejected for obviousness over U.S. Patent No. 5,464,650 to Berg et al.

The Examiner states that Berg teaches “a drug-containing expandable stent and method for making an intravascular stent by applying to the body of a stent a solution, which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent and then evaporating the solvent.” Processes for preparing the coated stent are also disclosed on column 3, line 52 - col. 4, line 34, wherein it is taught that a solution, which includes a solvent, polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent is first prepared.”

Berg does not teach, expressly or inherently, polymeric particles containing a therapeutic substance embedded in a coating. Berg teaches preparing a solution with a “polymer dissolved in a solvent” (col. 3, line 54), applying the solution to a stent, and then allowing the solution to evaporate. (col. 4, lines 19-20).

Berg does teach coating a stent with a solution containing solvent with a therapeutic substance “dispersed in fine particles.” (col. 3, line 64) In addition, Example 2 of Berg teaches dipping a stent in a “solution with suspended particles of dexamethasone.” (col. 5, lines 60-61) However, there is no indication by Berg or the Examiner that a coating with polymeric particles containing therapeutic agent embedded in the coating is formed. Thus, there is no express or inherent teaching or suggestion that the dispersed therapeutic agent is within polymer particles.

As with Yang, the Examiner stated a conclusion of a *prima facie* case of obvious without providing any support or argument for it. Furthermore, the Examiner has provided no motivation or suggestion to modify Berg so that it teaches the above-mentioned claim limitations.

The Examiner considered these arguments in the Final Office Action dated April 4, 2007 finding them unpersuasive and suggesting that Berg is "suggestive" of a polymeric matrix formed in a solution that traps the drug. (Col. 5, lines 12-18) A matrix formed in solution, however, is nonsensical. The Examiner has misunderstood Berg. Berg discloses different ratios of agent and polymer in solution that affect the ability to retain the agent on the stent, not different ratios that would somehow cause a matrix, or particles, to form in solution. Regardless, Berg doesn't teach or suggest particles containing a therapeutic agent either in solution or after deposition onto the stent.

Since the Examiner has failed to establish a *prima facie* case of obviousness, claims 25 and 32, and claims 26, 28, 29 and 30 dependent thereon, are allowable.

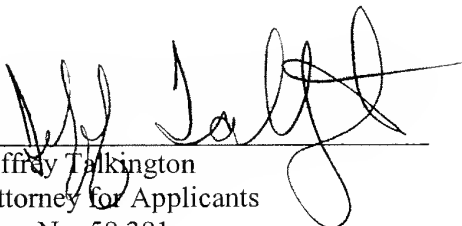
Applicants respectfully request that claims 25-33 be considered allowable and that the application pass to issue.

The undersigned authorizes the Examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

Respectfully submitted,

Date: May 29, 2006

Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza
Suite 300
San Francisco, CA 94111
Facsimile (415) 393-9887
Telephone (415) 954-0230


Jeffrey Talkington
Attorney for Applicants
Reg. No. 58,381